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148 DEN 8**Chemicals****Chemical Risk Review Details Expected From EPA by Fall***By Pat Rizzuto*

Chemical manufacturers this fall should have a better idea of the processes, models, and reasoning the EPA will use to determine whether new chemicals can be manufactured and sold in the U.S.

By September the Environmental Protection Agency plans to release documents detailing its new review process under the recently updated toxic substances law. Those would include its computer-based modeling and the assumptions it makes when it lacks sufficient information to evaluate a chemical's environmental and health effects, Jeffery Morris, director of the EPA Office of Pollution Prevention and Toxics (OPPT), said Aug. 2.

The documents are expected to aid companies as they prepare premanufacture notices (PMNs) they must submit when asking the agency to approve a new chemical, Charlie Auer, senior regulatory and policy adviser with Bergeson & Campbell, said. As a result, companies may be able to bring their products to market sooner.

For example the documents would explain how the EPA distinguishes between chemicals that "may pose an unreasonable risk" and could be subject to use restrictions or labeling requirements and those that are deemed "not likely to pose an unreasonable risk" and can be manufactured and sold, Morris said during a webinar hosted by Bloomberg BNA and Bergeson & Campbell, P.C.

The EPA also is preparing materials to clarify the amount and types of information about a new chemical that manufacturers should submit to avoid the agency deciding it has "insufficient information" to reach a conclusion about its health and environmental effects, Morris said.

The agency will discuss those documents during meetings it expects to hold in October or November, he said.

Chemical Categories Need Updates

Auer said it would be helpful if the EPA also updated the Chemical Categories Document it uses. The document groups together chemicals that—based on their solubility, volatility, or other properties—act in similar ways in the environment or in people's bodies. The agency lists concerns it may have about each chemical category and toxicity data that could help it address those concerns. The EPA published its most recent Chemical Categories Document in 2010.

"Times have changed," said Auer, who worked at the EPA for more than 30 years, including as a former OPPT director. Much of the information that's in the 2010 document is actually decades old, he said.

The EPA could update its chemical categories with new information it has gathered over the years and describe new types of toxicity and exposure tests companies could conduct that would provide valuable information, he said.

Bergeson & Campbell recently released comments on four new chemical categories the agency has shared with companies submitting the premanufacture notices and mentioned at public meetings. The agency's categories focus on potential respiratory problems that workers or other exposed people might experience if they inhaled chemicals with certain structures or chemicals that perturb lung cells in certain ways.

The EPA declined to release information about these four categories to Bloomberg BNA or to be

Snapshot

- EPA developing documents to explain process, rationale behind new chemical decisions
- Documents could aid manufacturers as they prepare requests to have chemicals evaluated

interviewed concerning them. "These draft documents were sent to a subset of PMN submitters for their input, and EPA is still awaiting individual comments from them," the agency said by email.

One-Sided Sharing?

Richard Denison, lead senior scientist with the Environmental Defense Fund, told Bloomberg BNA his organization is "very concerned that documents that effectively represent EPA policy proposals or decisions have only been shared with the industry, and that other stakeholders have neither been provided with the documents or given an opportunity to comment on them."

Workers, environmental health groups, scientists, and other individuals and organizations "cannot judge the extent to which such comments are influencing the evolution of these documents," he said. Given the amended Toxic Substances Control Act's intent to have the EPA be more transparent and accountable in its decision making "this is not a good sign," Denison said.

Morris said the agency is evaluating its existing and new categories, information it has on hand, and data it needs. The EPA also is discussing how to request toxicity or other data using the tiered approach described in the amended chemicals law, he said.

As it pulls together that information, it plans to make it public, Morris said.

Getting to Market Sooner

The documents the EPA plans to release by September combined with updated categories could help companies understand what they need to give the agency to get their chemicals to market sooner, Auer said.

But, the EPA needs to commit to finishing its new chemical reviews faster, he said. The agency has made significant progress since TSCA was amended in 2016 to make decisions concerning a backlog of new chemical requests that had built up immediately following passage of the new law, he said.

But once the EPA makes its decision, it's taking too long for companies to negotiate the types of controls that could be required for new chemicals, Auer said.

The agency should consider developing a clear process to address "adversarial" determinations when it and a manufacturer cannot agree on whether some type of control is needed, he said.

Morris said he agreed it's not useful for new chemical control negotiations to continue for months or years. The agency is continuing to work on ways to improve its new chemicals program, he said.

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